

**Conclusions:** Rotational aortography with CT reconstruction is feasible and can guide TAVR. Sizing at the nadir of the native valve cusps may be a useful modality complementary to transesophageal echocardiography for implant sizing to reduce prosthetic AI.

## TCT-866

# Transcatheter Aortic Valve Implantation in Patients With Bicuspid Aortic Valve Disease: Results from the Milan Registry

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**Background:** Transcatheter aortic valve implantation (TAVI) is a viable option for high-risk patients with severe symptomatic tricuspid aortic valve stenosis. However, the role of TAVI in the treatment of the stenosed bicuspid aortic valve has not been clearly demonstrated.

**Methods:** Consecutive patients with bicuspid aortic valve disease in our center treated with TAVI from November 2007 to May 2012 were included. All data was collected from a comprehensive prospective database and events were adjudicated according to the Valve Academic Research Consortium (VARC) definitions.

**Results:** In total, 8 patients undergoing TAVI were identified to have an anatomical bicuspid aortic valve. The mean age was  $75.8 \pm 5.5$  years and 75.0% were female. The patients were deemed high risk for surgery, with a median STS score of 6.5 (interquartile range [IQR] 3.7-13.8). Of the patients n=5 (62.5%) underwent implantation of the Medtronic CoreValve® ReValving system device (Medtronic Inc., Minneapolis, MN) and n=3 (37.5%) the Edwards SAPIENT™/SAPIENT XT™ (Edwards Lifesciences, Irvine, California). At 30 days, there were 2 deaths, both secondary to aortic dissection (one peri-procedural and one 24 hours post-procedure). There were no events of myocardial infarction or stroke. With regards to the procedure, there were no cases of device embolization. The overall VARC device success was n=6 (75.0%), with both failures due to residual significant aortic regurgitation. At a median of 435 (IQR 399-507) days follow-up, there was one further death secondary to hepatic failure. One other patient was readmitted to hospital at day 75 due to acute cardiac compensation. This resulted in a combined efficacy endpoint of 50.0% at follow-up.

**Conclusions:** Despite small numbers, the outcomes of TAVI for the stenosed bicuspid aortic valve may not be optimal and hence require further investigation prior to this becoming an acceptable treatment option in this group of patients.

## TCT-867

### Clinical Impact of Persistent Left Bundle Branch Block After CoreValve Revalving System Implantation. Insight from a Multicenter Italian Registry.

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**Background:** Conduction disturbances are relatively common after Transcatheter Aortic Valve Implantation (TAVI). Previous data demonstrated an adverse impact of persistent left bundle branch block (LBBB) after surgical aortic valve replacement. It is unclear whether a new onset LBBB may also impact on prognosis of patients after TAVI.

**Methods:** Among 1060 patients treated with CRS-TAVI between October 2007 and April 2011 in high volume centers in Italy, we considered those without LBBB nor Pace-Maker at admission (879 patients, 82.7%). Those who had received a PM within 48 hours from the procedure were then excluded (61 patients, 7%), resulting in a final study population of 818 patients.

**Results:** Among them, 224 patients (Group A, 27.3%) developed a persistent LBBB, the remaining 594 patients (Group B, 72.7%) did not. Clinical characteristics were similar between groups. In group A, a low implant was significantly more frequent (15% vs 9.8%,  $p=0.02$ ). At 30 days as well as at 1 year (mean follow up of  $266 \pm 248$  days, median 180 days), survival analyses and inherent log rank tests showed that LBBB was not associated with a higher all-cause mortality, cardiac mortality, hospitalization for heart failure. At 30 days, but not at 1 year, Group A had a significantly higher rate of PM implantation.

**Conclusions:** In this high volume centers registry, persistent LBBB post CRS-TAVI showed no effect on hard end points. On the other hand, LBBB was associated with a higher short term rate of PM implantation.

**TCT-868**

### Incidence, Predictors and Impact of Bleeding after Transcatheter Aortic Valve Implantation

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**Background:** Data regarding the determinants and outcomes of bleeding after transcatheter aortic valve implantation (TAVI) are limited. The purpose of this study was to evaluate the incidence, predictors and impact of bleeding after TAVI.

**Methods:** We included 250 consecutive patients (Pts) implanted in our center between May 2006 and Oct 2011. All procedures were performed using the Edwards SAPIEN and SAPIEN XT valves, via transfemoral (TF) and transapical (TA) routes. Surgical cutdown was performed for TF access with the SAPIEN valve (22-24 F introducers), while percutaneous closure (Prostar) was used with the SAPIEN XT valve (18-19F introducers). Ascendra 1 (28F) and Ascendra 2 (26F) delivery systems were used for TA TAVI. Dual antiplatelet therapy was administered prior to TF implantation, aspirin only in TA cases, with 70 UI/kg of unfractionated heparin after sheath insertion. Bleeding and other complications were defined using VARC criteria.

**Results:** TAVI was performed via TF route in 190 cases (76%), and SAPIEN XT was used in 123 Pts (49.2%). Bleeding after TAVI was observed in 68 Pts (27.2%) as follows: life-threatening bleeding (LTB) in 33 (13.2%), major bleeding in 23 (9.2%) and minor bleeding in 12 (4.8%). Bleeding was access related in 70%. After multivariate analysis, only TA access was an independent predictor of LTB (OR 3.35, 95% CI: 1.52–7.38,  $p < 0.003$ ). Pts presenting LTB had higher 30-day mortality: 33.3% vs. 3.7%,  $p < 0.001$  and 1-year mortality: 82% vs. 46%,  $p < 0.001$ . LTB was an independent predictor of 30-day (OR 6.98, 95% CI: 1.93–25.1,  $p = 0.003$ ) and 1-year mortality (HR 2.18, 95% CI: 1.11–4.28,  $p = 0.024$ ). Survival rate was similar in patients with and without major bleeding, at 30 days (0 vs. 8.4%,  $p = 0.23$ ) and 1 year (78.5% vs. 77%,  $p = 0.72$ ).

**Conclusions:** Bleeding after TAVI was observed in over 25% of cases and was mostly access-related. LTB was associated with higher 30-day and 1-year mortality.

## TCT-869

### Percutaneous clousure of para valvular aortic leak with AVPIII device, clinical follow-up late.

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**Background:** Percutaneous closure of paravalvular aortic leak (APL) has been presented as an alternative to reoperation. Objective: To describe our population undergoing percutaneous repair of APL with Amplatzer Vascular Plug III® (AVP III) and describe clinical events.

**Methods:** Prospective registry for all patients(p) who underwent percutaneous repair of at least 1 APL. AVPIII devise used.

**Results:** Twelve p, age  $67 \pm 14$  years. Number of aortic valve surgeries  $2.03 \pm 0.96$ . Interval time from last surgery to percutaneous closure was  $7.6 \pm 7.6$  years. Nine p had mechanical valve prostheses, 4p had also a mechanical mitral valve and presented a mitral paravalvular leak. Clinical presentation: 30% had heart failure, 10% hemolytic anemia and 60% both. NYHA functional class  $3 \pm 0.6$ , hematocrit  $28.7 \pm 5\%$ , Echo: LVEF  $60 \pm 9\%$ ; Systolic PAP:  $55 \pm 28$  mmHg; Numbers of APL 16; Degree of regurgitation  $3.2 \pm 0.8$ . Euroscore  $14 \pm 4$ . In 13 procedures, 13 APL was attempted; the wire was crossed retrograde in 12 APL, arteriovenous loop was established in 4p, in whom the delivery sheath was advanced antegrade. The procedure was successful in 11p and 11APL, 1.09 AVPIII devices were implanted, simultaneous mitral and aortic closure was done in 3p. Outcome of the procedure: decreased APL regurgitation to degree  $1 \pm 0.8$ . Periprocedural events: pacemaker 1p, femoral pseudoaneurysm 1p and mortality 1p (he did not have AVPIII deployed and died 3 days later of heart failure). Follow-up  $642 \pm 397$  days. Ninety one per cent of p with AVPIII have improvement of functional class in at least 1 grade, NYHA functional class  $2 \pm 0.9$  ( $p=0.01$ ), hematocrit  $35 \pm 4.3\%$  ( $p=0.03$ ) and APL regurgitation  $1 \pm 1.1$  ( $p=0.01$ ). Late clinical events: new intervention residual APL regurgitation in 2p (1p surgery at 246 days and 1p new percutaneous repair with new AVPIII at 727 days). Hospitalization for aortic regurgitation 2p, late mortality in 1p at 831 days of coronary artery disease.

**Conclusions:** Percutaneous closure of APL with AVPIII device is safe with high rate of immediate procedural success. Patients presented late clinical improvement in both

functional class and hematocrit and a significant decrease in aortic periprosthetic regurgitation.

# TCT-870

## Frailty Assessment Tools – Impact on short term outcome after TAVI

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**Background:** Older patients (pts) with aortic valve stenosis suitable for transcatheter aortic valve implantation (TAVI) have an increased operative risk due to advanced age and co-morbidities. However current risk scores have been shown not to be the ideal tool to predict postinterventional outcome in this population. Frailty especially seems to be one of the major factors not included into these scores. Therefore aim of this study was to elucidate whether frailty assessment helps to predict outcome after TAVI.

**Methods:** Pts were assessed prospectively regarding there over all appearance by two independent physicians and a numerical score from 1 (frail)-10 (good condition) was given. Additionally Katz activity score, gait speed testing, a five feet walk test and a hand grip strength test were performed. After 30days follow-up hemodynamic, clinical data as well as VARC safety endpoints were analysed.

**Results:** A total of 75pts (age 81±6years) with a logEuroSCORE of 20.6±12.7% were treated. Almost ¾ of the pts received a Medtronic CoreValve and 19 an Edwards SAPIEN XT, two of them as valve-in-valve. The prostheses were successfully implanted in all pts. The mean gradient declined from 67.0±12.3 to 12.0±7.5mmHg. VARC success was achieved in 97.3%. The combined safety endpoint occurred in 24%. One pt died due to intracranial haemorrhage and one major stroke was noted. Thus major stroke and death occurred in 2.67%. Mean appearance score was 6.3±1.7, mean Katz activity score 5.4±1.4. Mean time to overcome five-feet was measured 8.5±4.2s. Mean hand grip strength of the dominant hand was 20.2±8.5Kg. There was no significant predictive value of hand grip strength and Katz score using a regression analysis (p=0.938; 0.925-1.089; p=0.301; 0.526-1.222). The reduced walking speed failed to reach the level of significance in this relatively small cohort (p=0.06; 0.991-1.529). Only the overall appearance score had significant predictive value for the occurrence of the combined safety endpoint (p=0.015; 0.280-0.873).

**Conclusions:** TAVI in older pts with higher risk is safe, feasible and reliable. Frailty assessment provides additional information but individual clinical judgment remains crucial to insure beneficial outcome.

# TCT-871

## Leveraging Preparatory Balloon Aortic Valvuloplasty (BAV) During TAVI for Improved Valve Sizing – A simple way to reduce Paravalvular Aortic Regurgitation (PAR)??

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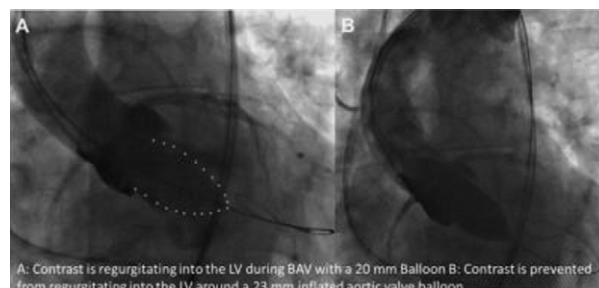
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**Background:** Valve-size selection for TAVI is based on annular measurements by echocardiography or CT. Still, relevant PAR with negative impact on survival is common(20%). We sought to evaluate whether supraaortic angiography during BAV may provide improved sizing(figure).

**Methods:** Data of 167 consecutive pts with conventional sizing (echo,CT) (group 1) were compared to 103 successive pts, in which BAV was, additionally leveraged for size-selection (group 2). PAR was graded angiographically (Sellers criteria) and quantitatively using the pressure difference between diastolic aortic pressure and LVEDP ( $\Delta P$  DAP-LVEDP) and the myocardial supply-demand ratio (DPTI:SPTI), a  $\Delta P$  DAP-LVEDP $\leq$ 18 mmHg and a DPTI:SPTI $\leq$ 0.7 having previously been proposed as cut-off values associated with increased cardiovascular mortality.

**Results:** TAVI was successful in all pts (ES:166,MCV:103), PAR was observed in 113pts of gp1 and 41pts of gp2 (67vs40%, p<0.05). At least Moderate PAR, a  $\Delta P$  DAP-LVEDP $\leq$ 18 mmHg and a DPTI:SPTI $\leq$ 0.7 were observed more frequently in gp1 than gp2: 14.4vs7.8%, 26.3vs14.5% and 11.9vs6.7% (p<0.05). According to preinterventional imaging, 40pts had a borderline annulus size, raising uncertainty regarding valve-size selection. Balloon-sizing resulted in selection of the “bigger” prosthesis in 21pts; only 2 of these pts had relevant PAR. Cardiovascular mortality at 30 days&1-year was significantly decreased in gp2 compared to gp1 (5.8vs9% & 10.6vs20%, p<0.05).(no BAV-complications).

**Conclusions:** Preparatory BAV during TAVI can be leveraged to improve valve-size selection and reduce associated PAR, especially in borderline cases.



# TCT-872

## Results of transfemoral TAVI in Partner-like Patients – A comparison with Real-World Patients

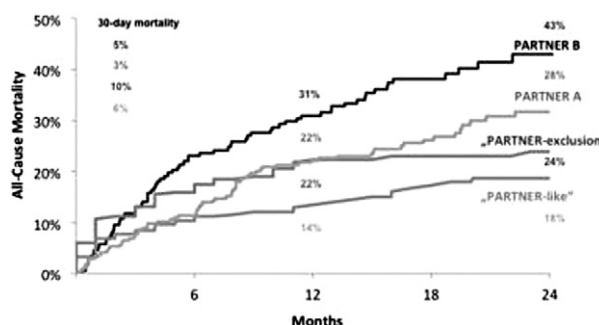
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**Background:** TAVI is currently transforming the treatment of non-operable and high-risk pts. with aortic stenosis, and the randomized PARTNER trial has shown excellent results. Notably, several pts. with comorbid conditions, which are frequently encountered in a real-world setting, were excluded. However, such pts. are already treated in countries with CE-approval. We report our two-center transfemoral (TF) TAVI-experience with focus on the comparison between real-world and PARTNER-like patients.

**Methods:** Over 6 years (2006-11) 485 pts. (age: 80±7;EuroSCORE: 22±16%) underwent TF TAVI (ES 176; MCV 309). Patients were divided into a “PARTNER-like” and a “PARTNER-exclusion” group based on PARTNER B inclusion criteria. Differences in 30-day, 1- and 2-year mortality were assessed.

**Results:** 213 pts. would have been excluded from PARTNER B, most frequent exclusion criteria being prior valve surgery (16%), chronic renal failure (14%), severe mitral regurgitation (11%), reduced LV-EF (9%) and prior PCI (6%). Pts. in the “PARTNER-exclusion” group had a higher 1- and 2-year mortality than in the “PARTNER-like” group, and a non-significant trend towards an increased 30-day mortality. Compared to PARTNER-data, “PARTNER-like” pts. had a slightly higher 30-day, but a markedly lower 2-year mortality. Interestingly, 2-year mortality was also lower in excluded pts. despite a two-fold 30-day mortality.



**Conclusions:** In our real-world experience, 44% of TAVI pts. did not meet PARTNER inclusion criteria. Although these pts. had a comparatively high early hazard, the late outcome benefit was, interestingly, better than reported for PARTNER.

# TCT-873

## Results of Transfemoral Aortic Valve Implantation (TF-TAVI) performed by External Cardiologists in Collaboration with an Experienced Multidisciplinary Heart Team at a Specialized Center

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**Background:** TAVI is currently performed with excellent results by dedicated, multidisciplinary heart teams at highly specialized centers. In the real-world, a substantial